A Novel Technique for Multi-Track Percutaneous Balloon Mitral Valvoplasty

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Summary

Percutaneous balloon mitral valvoplasty (PBMV) has become the treatment of choice for severe pliable rheumatic mitral stenosis. The multi-track system is a recent variation of the double-balloon technique and is easier owing to the use of a monorail balloon and a simple, single-guidewire approach. In the present study, we used the double-coil Inoue metal wire with a multi-track balloon instead of the conventional multi-track wire. We studied 62 consecutive patients (55 females) with significant symptomatic rheumatic mitral valve stenosis who underwent multi-track PBMV. Patients were randomized into 2 groups: the first group included 32 patients treated with the novel multi-track technique using the double-coil Inoue metal wire, and the second group included 30 patients treated with the conventional multi-track technique using a balloon endhole catheter and multi-track 0.035 inch stiff wire. None of the patients had cardiac tamponade, systemic thromboembolism, or any groin complications. No statistically significant differences were found between the 2 groups regarding any of the studied variables. There were no in-hospital deaths or complications necessitating emergent cardiac surgery in either group. In conclusion, this new technique with the double-coil Inoue metal wire achieves the double benefit of being as safe as (and indeed easier than) the conventional technique, and it utilizes fewer materials, making the multi-track system more cost-effective. (Int Heart J 2013; 54: 196-201)

Key words: Inoue, Endhole, Rheumatic, Stenosis

Rheumatic mitral valve stenosis remains an important public health concern in developed countries.[1)] When there is favorable mitral valve anatomy, percutaneous balloon mitral valvoplasty (PBMV) has become the treatment of choice for severe pliable rheumatic mitral stenosis.[2)] With increasing experience and better selection of patients, the immediate results of the procedure have improved, and the rate of complications has declined.[2)] Several randomized trials reported similar hemodynamic results with PBMV and surgical commissurotomy.[1,3-6)]

There are currently 2 main techniques for PBMV: balloon commissurotomy and metallic commissurotomy. In balloon commissurotomy, the 2 main modalities are the double-balloon technique and the Inoue technique. The double-balloon technique is effective but demanding and carries a risk of left ventricular perforation by the guidewires or the tips of the balloons.[7)]

The multi-track operator-friendly system is a recent variation of the double-balloon technique. This system has the advantages of the double-balloon technique and is also an easier procedure because of the use of a monorail balloon and a simple, single-guidewire approach.[7,8)] The procedure time is similar to that of single-balloon techniques while achieving consistently higher mitral valve area postdilatation.[7)] The mismatch between the round shape of a single balloon and the oval mitral valve orifice probably explains the better results that have been reported with double-balloon dilatation.[8)]

The Inoue technique, on the other hand, allows for stepwise dilatation (as it is pressure extensible), leading to safe and rapid positioning across the mitral valve.[7)] In the present study, we modified the PBMV procedure via using the double-coil Inoue metal wire with a multi-track balloon instead of the conventional multi-track (Super Stiff, preformed 0.035 inch) guidewire to achieve the double benefit of the safety of the double-coil Inoue metal wire and the ease of its use. This technique also utilizes fewer materials, making it more cost-effective.

Methods

Study design and participants: The study population consisted of 62 consecutive patients with significant symptomatic rheumatic mitral stenosis (mitral valve area < 1.5 cm^2) who underwent multi-track PBMV solely under fluoroscopic guidance in our institute between January 2010 and December 2011.

A patient was excluded if any of the following 7 exclusion criteria applied: (1) left atrial cavitary thrombus or unstable (eg, pedunculated mobile) thrombus in the left atrial appendage; (2) severe mitral valve regurgitation (vena contracta on color flow mapping of > 6 mm); (3) severe aortic stenosis (aortic orifice area of < 0.7 cm^2, as calculated by the continuity

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equation); (4) severe aortic regurgitation (the width of the aortic regurgitation jet > 50% of the width of the left ventricular outflow tract); (5) evidence of significant coronary artery disease (history of myocardial infarction, typical effort angina, or the presence of significant atherosclerotic lesions in the proximal coronary arteries or aorta, as demonstrated by transesophageal echocardiography); (6) active systemic infection; or (7) active cerebral hemorrhage or embolism. These patients were divided into 2 groups: the first group with the double-coil Inoue metal wire (novel Inoue technique group) and the other group with the conventional multi-track wire (conventional endhole technique group).

The study protocol was reviewed and accepted by the local Ethical Review Board of Mansoura Faculty of Medicine, and written informed consent to participate in this study was obtained from all patients before the PBMV procedure. The authors declare the presence of no conflicts of interest.

Pre- and post-procedural echocardiographic evaluations: Detailed transesophageal and transthoracic echocardiographic examinations were done for all patients using a real-time phased-array sector scanner (Vivid-3 model) with an integrated color Doppler system for imaging at 2.5–4.0 MHz with second harmonic capabilities. For continuous and pulsed-wave Doppler studies, the transducer emitted at 1.9 MHz. Transesophageal echocardiography was interfaced with a 5-MHz multiplane probe mounted on an endoscope.

The pre-procedural examination was performed within 48 hours of undergoing PBMV. Post-procedural echocardiographic assessment was also carried out. The pre-procedural and post-procedural mitral valve orifice areas were accurately measured by planimetry using 2-dimensional transthoracic echocardiography. The peak and mean pressure gradients across the mitral valve were recorded, and pulmonary artery systolic pressure was estimated using tricuspid regurgitation Doppler signal velocity. Morphologic changes of the mitral valve and the mitral valve score were evaluated by the method of Wilkins, *et al*.[9]

The multi-track kit:[8] The kit for mitral dilatation included 5 components (Multi-Track, Mitral dilatation kit, NuMED, Hopkinton, NY): 2 balloon catheters, a multi-track angiographic catheter, a guidewire, and a septal dilator. The system allows the operator to load 2 balloon catheters on the same wire. The multi-track angiographic catheter has side holes as a functional unit, which enables pressure measurements during the procedure without guidewire removal. Both balloon catheters have stainless steel shafts connected to nylon tubing. The multi-track balloon has a 10-cm plastic shaft and a multi-track tip at its end. The other balloon catheter has a standard monorail catheter that is 16 cm in length. The guidewire is an extra-stiff 0.035 inch (0.035″) wire with a 6-cm floppy J-tip with a preformed curve adapted for deployment at the left ventricular apex. The septal dilator is 14 Fr tubing (length, 65 cm) with a lumen large enough for the guidewire and a tapered tip.

Valvoplasty procedure:[10] The right groin was used for vascular access (two 6F sheaths for arterial and venous access). A pigtail catheter was advanced into the aortic root and connected to a pressure line for monitoring purposes. A 0.035″ guidewire was introduced through the venous sheath and advanced into the left innominate vein. A 7F Mullin's dilator (St. Jude's Medical, Minnetonka, MN) was advanced over this wire to the left innominate vein in the same view. The 0.035″ guidewire was exchanged with a Brockenbrough needle that was passed from the left innominate vein to the superior vena cava to slide over the interatrial septum and was advanced within the Mullin's dilator just short of its tip. The assembly of the Brockenbrough needle and the Mullin's dilator was then manipulated in the right atrium in antero-posterior and lateral views with the index of the Brockenbrough needle pointing postero-medially (4 or 5 o'clock position) at the groin until the tip of the Mullin's dilator was tented midseptum at or below (but not posterior to[11]) the fossa ovalis (to facilitate catheterization through the stenotic mitral valve). Atrial septostomy was then performed.

After entry of the needle into the left atrium was confirmed, first by contrast medium injection followed by pressure recording, the needle direction was set toward 3 o'clock (left side of the patient). If there was little or no resistance, the catheter needle was advanced forward about 2 cm into the left atrium. Then, the catheter alone was advanced another 2 cm (or until the tip of the sheath met resistance at the septum) while the needle was being withdrawn. Upon removal of the needle, after the catheter was placed in the left atrium, 100 IU/kg heparin was given immediately through the catheter. After baseline hemodynamic studies, PBMV was performed.

The conventional multi-track technique:[8] A balloon endhole catheter was introduced into the Mullin's sheath and advanced into the left atrium. Before passing through the mitral valve, the balloon of this catheter was inflated to avoid its entrapment in the subvalvular apparatus. The mitral valve was then catheterized either directly, orienting the catheter slightly anteriorly, or by a more indirect approach, allowing the catheter to form a large loop in the left atrium. After the balloon endhole catheter was passed through the mitral valve, it was advanced to the apex of the left ventricle, and the catheter was then straightened to obtain a harmonious curve on its shaft. The 0.035″ stiff guidewire with a 6-cm floppy J-tip was then positioned through this catheter. Particular attention was paid to allow the J to develop freely when exiting the tip of the catheter. After full deployment of the J, the wire was pushed into the left ventricle until a good guidewire position was obtained. The guidewire position was considered adequate when the entire 6 cm of the floppy tip was pointing upward toward the left ventricular outflow and the curve in the left atrium was as flat as possible. Then the balloon was deflated, and the catheter was retrieved with the Mullin's sheath. The skin and the atrial septum were then dilated with a 14 Fr long dilator.

The balloons of the multi-track system were prepared at this time by drawing a vacuum and removing air bubbles from each balloon lumen. The syringe was then disconnected and filled with a mixture of contrast medium and saline solution and reconnected to the balloon catheters. The septal dilator was then withdrawn, and the balloons were loaded onto the guidewire. The first multi-track balloon was introduced through the skin and atrial septum and positioned in the mitral valve. The second balloon was then advanced over the wire and lined up with the first one in the mitral valve. More than half of the balloon length was positioned in the left ventricle before inflation. However, attention was paid so that the tip of the multi-track catheter did not advance onto the floppy part of the wire. The balloons were then inflated simultaneously under fluoroscopic guidance. The waist disappeared from view at this time, and the adequate position in the mitral valve was con-

firmed. After deflation, the balloons were sequentially removed under fluoroscopic guidance. After removal of the balloon on the wire, the multi-track balloon was retrieved while maintaining a parallel orientation to the guidewire. To assess the results, the pigtail catheter was again introduced into the left ventricle, and a multi-track angiographic catheter was connected to the wire and advanced into the left atrium. If the diastolic gradient was not satisfactory, different balloon sizes of multi-track catheters could be introduced over the wire at this time. Otherwise, with an acceptable transmitral gradient, the wire was pulled into the left atrium, leaving the multi-track angiographic catheter in the left atrium, and the measurements were repeated. This avoided the need to record mitral regurgitation related to the guidewire in the mitral valve. Figure 1 shows the main steps of this conventional technique.

The novel multi-track technique: From our experience, the double-coiled stainless-steel Inoue wire can pass through the mitral valve to the left ventricle via Mullin's sheath and dilator. After removing the needle from the Mullin's dilator, the double-coil metal wire of the Inoue system (Toray Industries Inc., Tokyo) was introduced through the Mullin's dilator into the left atrium. With advancement of the sheath before the dilator to direct the wire towards the mitral valve orifice, we could cross the mitral valve into the left ventricle via the double-looped wire instead of the balloon endhole catheter. The loops of the round wire could be easily visualized in the left ventricle under fluoroscopy. However, concern regarding wire-induced arrhythmia, perforation, or entrapment in the subvalvular apparatus remains an issue. Nevertheless, apical perforation by this wire is almost completely avoided because of its double-coil. To ensure that the wire is not entrapped in the subvalvular apparatus, this double-coil wire should reach the left ventricular apex with a free to-and-fro movement in the left ventricular cavity. The remaining steps are essentially the same as in the conventional technique described above. Figure 2 shows the main steps of the novel technique (comparing Figures 1 and 2 clearly shows that the novel technique has fewer steps, saves the cost of using an extra-catheter, and has a safer wire profile than the 0.035″ stiff wire).

Results

We studied 62 patients (55 females; 88.7%) with significant symptomatic rheumatic mitral stenosis who were randomized into 2 groups. The first group included 32 patients (29 females; 90.6%; age 36.5 ± 9.2 years) treated with the novel multi-track technique using the double-coil Inoue metal wire. The second group included 30 patients (26 females; 86.7%; age 37.3 ± 13.1 years) treated with the conventional multi-

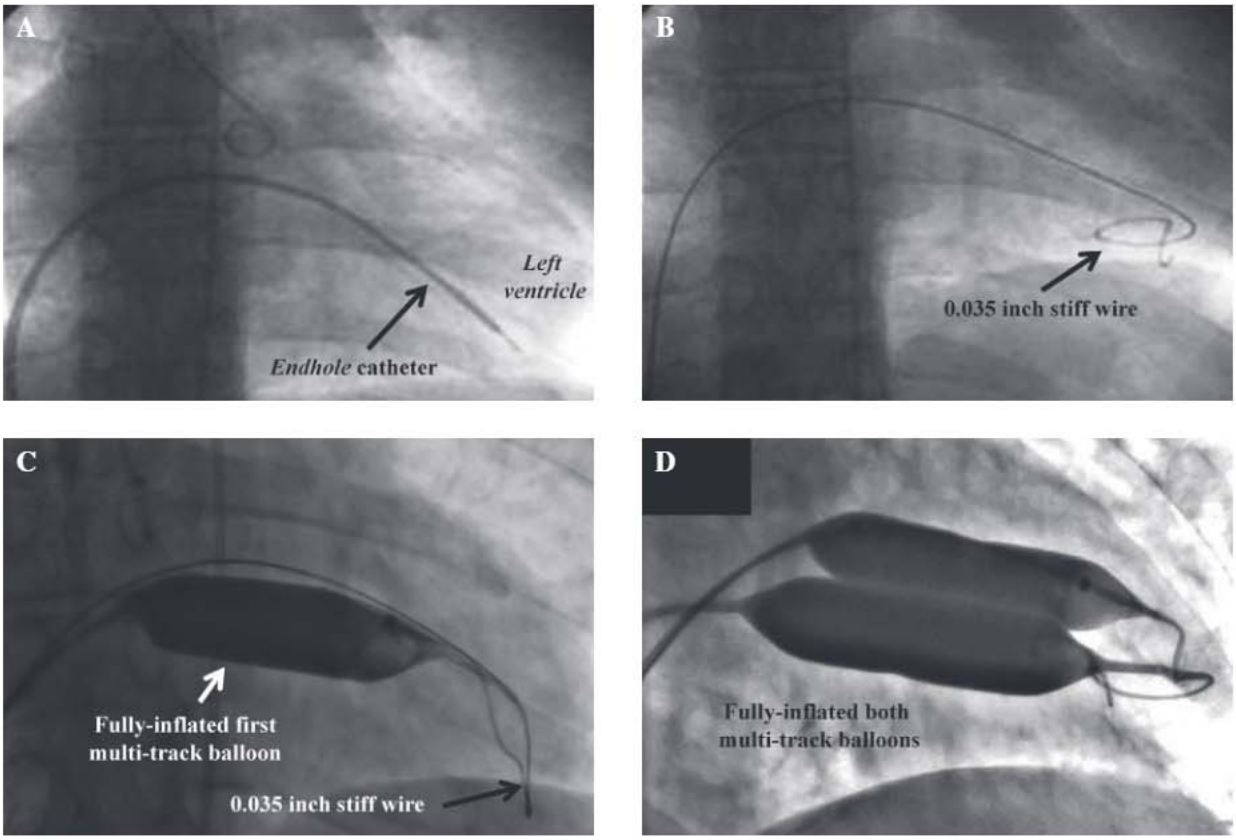

Figure 1. A: Anteroposterior (AP) view showing the endhole catheter tip positioned in the left ventricular apex. **B:** AP view showing the 0.035″ stiff guidewire passing through the endhole catheter to the apex of the left ventricle with its tip directed towards the left ventricular outflow tract. **C:** AP view showing the first monorail multi-track balloon fully inflated at the mitral valve apparatus over 0.035″ stiff guidewire with its 6-cm floppy J-tip pointing upward towards the left ventricular outflow. **D:** AP view showing both multi-track balloons fully inflated over the 0.035″ stiff guidewire at the mitral valve apparatus with complete disappearance of the balloon waist. PS: panels (A) and (B) of Figure 1: courtesy of Dr. Mohamed Sadaka.

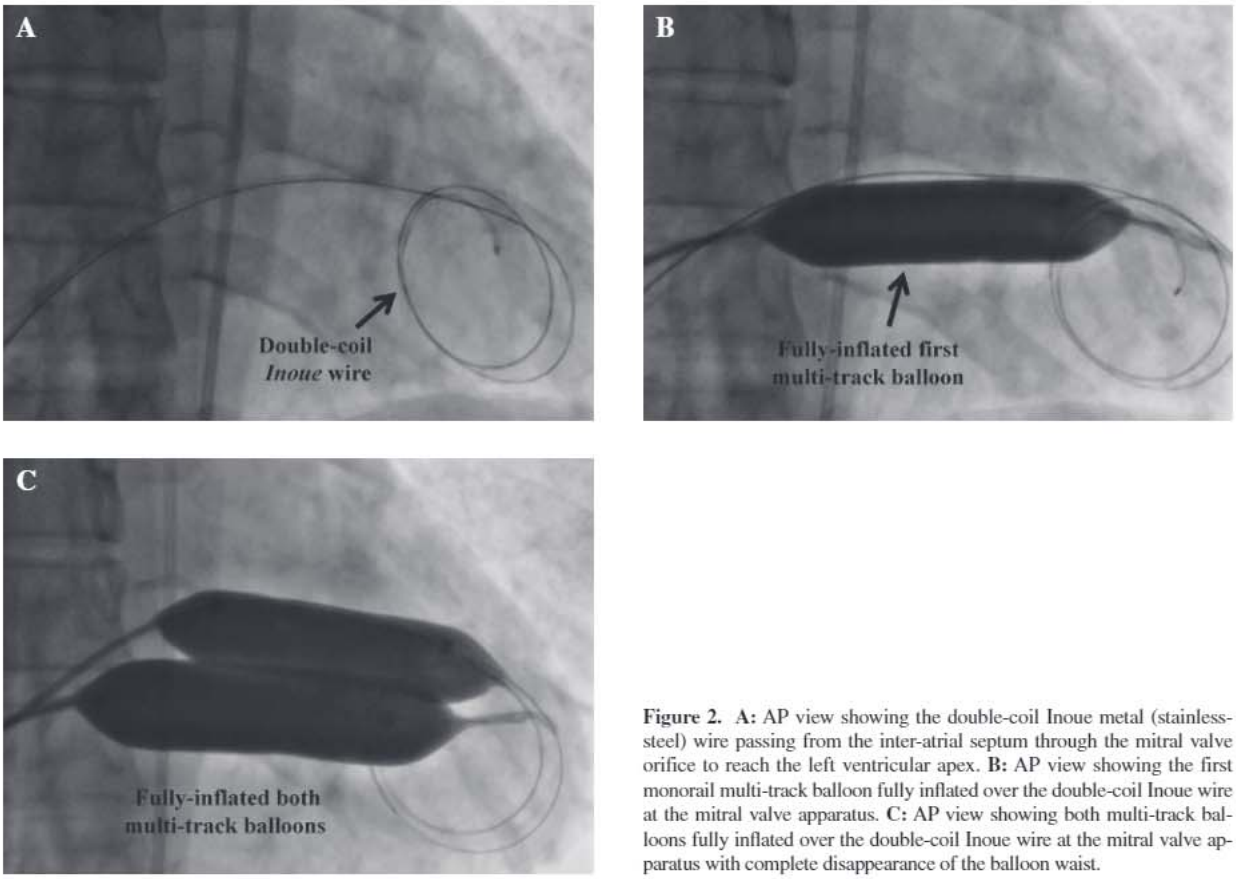

Figure 2. **A:** AP view showing the double-coil Inoue metal (stainless-steel) wire passing from the inter-atrial septum through the mitral valve orifice to reach the left ventricular apex. **B:** AP view showing the first monorail multi-track balloon fully inflated over the double-coil Inoue wire at the mitral valve apparatus. **C:** AP view showing both multi-track balloons fully inflated over the double-coil Inoue wire at the mitral valve apparatus with complete disappearance of the balloon waist.

Table I. Baseline Demographic, Clinical, and Echocardiographic Data of the Study Groups

	Novel Inoue technique ($n = 32$)	Conventional endhole technique ($n = 30$)	*P*
Demographic data			
Age (years)	36.5 ± 9.2	37.3 ± 13.1	0.781
Gender			
Male	3 (9.4%)	4 (13.3%)	0.933
Female	29 (90.6%)	26 (86.7%)	
Clinical data			
NYHA class			
II	8 (25.0%)	10 (33.3%)	0.660
III	24 (75.0%)	20 (66.7%)	
Atrial fibrillation	8 (25.0%)	9 (30.0%)	0.876
Previous MV dilatation	4 (12.5%)	3 (10.0%)	0.928
Echo data			
MV score	7.27 ± 1.16	7.14 ± 1.36	0.686
Left atrial diameter (cm)	4.97 ± 0.45	5.17 ± 0.64	0.158
LVESD (cm)	2.89 ± 0.31	3.01 ± 0.33	0.145
LVEDD (cm)	4.65 ± 0.38	4.71 ± 0.31	0.501
Aortic regurgitation			
None or trivial	28 (86.4%)	27 (90.9%)	0.875
Grade I	4 (13.6%)	3 (9.1%)	

LVEDD indicates left ventricular end diastolic dimension; LVESD, left ventricular end systolic dimension; MV, mitral valve; and NYHA, New York Heart Association.

track technique using the 0.035″ stiff guidewire and endhole catheter. Table I shows the demographic, clinical, and echocardiographic data for both groups at baseline. No significant statistical differences were found between the groups regarding any of these variables. The majority of patients (44; 71%) had New York Heart Association (NYHA) class III dyspnea, and 17 patients (27%) had chronic AF on presentation: 8 (25%) in the Inoue group and 9 (30%) in the endhole group. Only 7 pa-

Table II. Comparative Analysis of Pre- and Post-Procedural Data of the Study Groups

	Novel Inoue technique ($n = 32$)	Conventional endhole technique ($n = 30$)	*P*
MV area (cm^2) by planimetry			
Pre-dilatation	1.02 ± 0.14	1.07 ± 0.17	0.209
Post-dilatation	2.01 ± 0.42	2.13 ± 0.45	0.282
Mitral regurgitation			
Pre-dilatation			
None or trivial	23 (71.9%)	20 (66.7%)	0.866
Grade I	9 (28.1%)	10 (33.3%)	
Post-dilatation			
None or trivial	7 (21.9%)	4 (13.3%)	0.150
Grade I	15 (46.9%)	13 (43.3%)	
Grade I–II	9 (28.1%)	11 (36.7%)	
Grade II–III	1 (3.1%)	2 (6.7%)	
Trans-mitral pressure gradient (mmHg)			
Pre-dilatation			
Peak pressure gradient	22.4 ± 5.2	24.6 ± 5.6	0.114
Mean pressure gradient	12.6 ± 3.13	13.7 ± 4.32	0.253
Post-dilatation			
Peak pressure gradient	12.8 ± 3.15	11.9 ± 2.12	0.195
Mean pressure gradient	6.5 ± 2.4	5.8 ± 1.4	0.169
PASP (mmHg)			
Pre-dilatation	37.9 ± 16.2	38.3 ± 15.3	0.921
Post-dilatation	30.1 ± 14.6	30.2 ± 12.5	0.977

MV indicates mitral valve and PASP, pulmonary artery systolic pressure.

tients (11%) had previous PBMV: 4 (12.5%) in the Inoue group and 3 (10%) in the endhole group.

Self-limiting non-sustained ventricular tachycardia of no hemodynamic or clinical significance occurred in 9 (14.5%) patients: 5 (16%) in the Inoue group and 4 (13%) in the endhole group ($P = 0.917$). Failed multi-track PBMV occurred in just 4 cases (2 in each group); these patients underwent successful dilatation with the Inoue balloon. The reasons for this failure included the inability to pass the wire across the mitral valve orifice in 2 cases (1 in each method), and the failure to stabilize the double-balloon over the wire that passed through the mitral valve orifice in the remaining 2 cases.

Table II summarizes the pre- and post-procedural findings and comparisons of the study groups. No statistically significant differences were found between the groups in any of these variables. Overall, the mitral valve area increased significantly after PBMV, from 1.02 ± 0.14 to 2.01 ± 0.42 cm^2 ($P < 0.001$) in the Inoue group, and from 1.07 ± 0.17 to 2.13 ± 0.45 cm^2 ($P < 0.001$) in the endhole group. Also, there was a significant reduction in the mean transmitral pressure gradient, from 12.6 ± 3.13 to 6.5 ± 2.4 mmHg ($P < 0.001$) in the Inoue group, and from 13.7 ± 4.32 to 5.8 ± 1.40 mmHg ($P < 0.001$) in the endhole group.

Before PBMV, 43 patients (69%) had trivial or no MR, and 19 (31%) patients had grade I MR. After PBMV, 11 patients (18%) had trivial or no MR, 28 (45.2%) had grade I MR, 20 (32.3%) developed grade I–II MR [9 (28.1%) in the Inoue group, and 11 (36.7%) in the endhole group], 3 (4.8%) developed grade II–III MR, and none developed severe MR necessitating surgery. Notably, pulmonary artery systolic pressure dropped significantly after PBMV, from 37.9 ± 16.2 to 30.1 ± 14.6 mmHg ($P = 0.047$) in the Inoue group, and from 38.3 ± 15.3 to 30.2 ± 12.5 mmHg ($P = 0.029$) in the endhole group.

A knot formed on the Inoue wire in 2 cases without any further procedural complications. The knot formed over the Inoue wire proximal to the balloon and was detected after mitral valve dilatation during removal of the balloon from over the wire at the end of the procedure. Management of knot formation was simply done by retraction of both balloon and wire together, which resulted in no vascular complications. None of the patients had cardiac tamponade, systemic thromboembolism, or any groin complications. There were no in-hospital deaths or complications necessitating emergent cardiac surgery.

Discussion

This study is the first to use the Inoue metal wire for PBMV with the multi-track system. The Inoue technique has become the most popular worldwide.[10] The design of the Inoue balloon allows safe and rapid positioning across the valve. In addition, it is pressure extensible, allowing step-wise dilatation.[7] The available data comparing the Inoue technique and the double-balloon technique suggest that the Inoue technique makes the procedure easier, that both have equivalent efficacy (although the double-balloon technique may result in a slightly larger valve area), that the long-term results are equivalent, and that the Inoue balloon carries a lower risk because left ventricular perforation is almost completely avoided.[7]

Traditionally, PBMV using multi-track double-balloons was always done with a Super Stiff preformed 0.035″ guidewire. The double-balloon technique is effective but technically demanding and carries the risk of left ventricular perforation by the guidewires or the tips of the balloons. The multi-track is a recent variant of the double-balloon technique and aims to make the procedure easier by using a monorail balloon and only a single guidewire.[7] This technique has the advantages of

the double-balloon technique in addition to the fact that the procedure times are similar to those of the single balloon technique while consistently achieving a higher mitral valve area post-dilatation. The mismatch between the round shape of a single balloon and the oval mitral orifice probably explains the previously reported better results with double-balloon dilatation.[8]

The conventional 0.035″ multi-track guidewire requires a balloon endhole catheter to enable its passage from the left atrium to the left ventricle after septostomy.[8] Some centers (including ours) use the right Judkins catheter to pass from the left atrium to the left ventricle, a technique that is more traumatizing than the endhole catheter. In addition, there is concern regarding entrapment in the subvalvular apparatus and an increased incidence of left ventricular perforation. The metal wire of the Inoue balloon used in this study is unlikely to become trapped in the subvalvular apparatus because of its free to-and-fro movement in the left ventricular cavity, or to cause left ventricular apical perforation because of its double coil. Thus, the incidence of traumatic injuries with the multi-track system is minimized with the Inoue wire.

In our study, there was no difference between the 2 groups regarding short-term results of PBMV, with no cases of left ventricular perforation, cardiac tamponade, or severe mitral regurgitation necessitating surgical intervention.

The cost of PBMV is a substantial problem for treating mitral stenosis because this disease is endemic in low-socioeconomic populations. To solve this issue, Cribier, *et al*[12] and Arora, *et al*[13] have developed a percutaneous metallic device for mitral valve dilatation that can be autoclaved and reused. In fact, the cost of the multi-track system is reduced owing to the simplicity of the system.[8] In addition to the economic advantages of the multi-track system described above, our new technique is far more cost-effective because it uses fewer materials and takes less time. The balloon endhole catheter is costly, but the Inoue wire can be reused after sterilization.

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